Docket No.: PC-0032 US

Response Under 37 C.F.R. 1.116 - Expedited Procedure
Examining Group 1642

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By: _____ Printed: Jeannie G. Labra

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of: Reddy et al.

Title:	ASIP-RELATED PROTEINS		
Serial No.:	09/757,781	Filing Date:	January 09, 2001
Examiner:	Rawlings, S.	Group Art Unit:	1642

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BRIEF ON APPEAL

Sir:

Further to the Notice of Appeal filed September 30, 2003, and received by the USPTO onDecember 6, 2003, herewith are three copies of Appellants' Brief on Appeal. Authorized fees include the $ **330.00** fee for the filing of this Brief.

This is an appeal from the decision of the Examiner finally rejecting claims 1 and 3-8 of the above-identified application.

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(1) REAL PARTY IN INTEREST

The above-identified application is assigned of record to Incyte Pharmaceuticals, Inc., (now Incyte Corporation, formerly known as Incyte Genomics, Inc.) (Reel 011774, Frame 0877) which is the real party in interest herein.

(2) RELATED APPEALS AND INTERFERENCES

Appellants, their legal representative and the assignee are not aware of any related appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the instant appeal.

(3) STATUS OF THE CLAIMS

Claims rejected:	Claims 1 and 3-8
Claims allowed:	(none)
Claims canceled:	Claims 2 and 15-22
Claims withdrawn:	Claims 9-14
Claims on Appeal:	Claims 1 and 3-8 (A copy of the claims on appeal, as amended, can be found in the attached Appendix).

(4) STATUS OF AMENDMENTS AFTER FINAL

Claims 3 and 4 were amended in the Response to Final Office Action filed 8/21/2003 to place the application is better condition of allowance or appeal by complying with the Examiners' remarks on the rejection of these claims under 35 U.S.C. § 112, first paragraph at page 10-11 of the Final Office
Action.

(5) SUMMARY OF THE INVENTION

Appellants' invention is directed to an isolated cDNA encoding a polypeptide of SEQ ID NO:2, a variant of SEQ ID NO:2 having at least 95% identity to SEQ ID NO:2 and specific antigenic epitope of SEQ ID NO:2. The invention is also directed to an isolated cDNA of SEQ ID NO:20, a fragment of SEQ ID NO:20 consisting of SEQ ID NO:21, or a naturally occurring variant of SEQ ID NO:20 having at least 90% sequence identity to SEQ ID NO:20. SEQ ID NO:2 is identified in the specification as an atypical protein kinase C isotype specific interacting protein (ASIP) by high sequence identity with known ASIP proteins (89% to 93% sequence identity), and by conservation of various structural and functional sequence motifs associated with ASIPs. See specification, at pp 10-11. ASIPs are described in the specification and the art

of record as proteins that interact specifically with atypical protein kinase C (aPKC) and therefore may have a role in various cellular signaling involving aPKC. See specification, at pp. 1-2. The polynucleotides encoding SEQ ID NO:2 are further disclosed in the specification as differentially expressed in bladder cancer and breast cancer relative to the corresponding normal tissues. See specification at page 11 and Tables 2 and 3. The claimed polynucleotides are therefore asserted to be useful in the diagnosis and treatment cancers of the bladder and breast, and in monitoring therapeutic intervention for these diseases. See specification, at pp. 19 and 20.

(6) ISSUES

1. Whether claims 1 and 3-8 directed to polynucleotides encoding ASIP-related proteins, and variants thereof meet the written description requirement of 35 U.S.C. 112, first paragraph. In particular, whether the specification sufficiently describes polynucleotides encoding a variant of SEQ ID NO:2 having at least 95% identity to SEQ ID NO:2, or a variant of SEQ ID NO:20 having at least 90% sequence identity to SEQ ID NO:20 that one of skill in the art would recognize applicants possession of said polynucleotides at the time the application was filed.

2. Whether claims 1 and 4-8 directed to polynucleotides encoding ASIP-related proteins, and variants thereof meet the written description requirement of 35 U.S.C. 112, first paragraph. In particular, whether there is sufficient antecedent basis in the specification for the recitation of "a naturally occurring variant" of [...] SEQ ID NO:2 and "a naturally occurring variant" of [...] SEQ ID NO:20", as recited in claims 1 and 4, respectively.

3. Whether claims 3 and 4 directed to polynucleotides encoding an antigenic epitope of SEQ ID NO:2 "from about amino acid residue K189 to about amino acid residue Q236..." (claim 3), and an isolated cDNA "comprising" a sequence...(claim 4) meet the written description requirement of 35 U.S.C. 112, first paragraph. In particular, whether there is sufficient antecedent basis in the specification for the recitation of these terms in the claims.

4. Whether claim 4 is anticipated under 35 U.S.C. § 102(a) by Joberty et al. In particular, whether the recitation of "a nucleic acid sequence of SEQ ID NO:20" in claim 4 is anticipated by the nucleic acid molecule of the prior art comprising one or more sequences of the polynucleotide sequence set forth in SEQ ID NO:20.

5. Whether claim 4 is anticipated under 35 U.S.C. § 102(b) by either Izumi et al. or NCI-CGAP, Data base GenBank Accession No. AI079538. In particular, whether the recitation of "a nucleic acid sequence of SEQ ID NO:20" in claim 4 is anticipated by the nucleic acid molecule of the prior art comprising one or more sequences of the polynucleotide sequence set forth in SEQ ID NO:20.

(7) GROUPING OF THE CLAIMS

As to Issue 1

All of the claims on appeal are grouped together.

As to Issue 2

Claims 1 and 4-8 stand together.

As to Issue 3

Claims 3 and 4 stand together.

As to Issue 4

Claim 4 stands alone.

As to Issue 5

Claim 4 stands alone.

(8) APPELLANTS' ARGUMENTS

Claims 1 and 3-8 stand rejected under 35 U.S.C.§ 112, first paragraph, as containing subject matter which was not described in the specification in such a way to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection alleges in particular that:

- Claim 1 is drawn to a cDNA encoding "a naturally occurring variant" of the polypeptide of SEQ ID NO:2; and claim 3 is drawn to a cDNA comprising a sequence of "a naturally

occurring variant" of SEQ ID NO:20. The specification does not describe a description of the structure of the nucleic acid molecule encoding a variant of the polypeptide of SEQ ID NO:2 having an amino acid sequence that is at least 95% identical to SEQ ID NO:2; not does the specification describe a cDNA molecule comprising the polynucleotide sequence of SEQ ID NO:20 having at least 90% identity to SEQ ID NO:20. As such, the description of the claimed invention would not be sufficient to reasonably convey to the skilled artisan that applicants had possession of the claimed invention at the time the application was filed. The Final Office Action further stated that based on a alleged uncertainty in assigning functional activity to a protein based on structural similarity, one skilled in the art would not accept the assertion, that a variant of SEQ ID NO:2 would be found to be functionally identical to the polypeptide of SEQ ID NO:2.

The rejection of claims 1 and 3-9 is improper as the inventions of those claims are sufficiently described in chemical and structural terms that one of skill in the art would recognize applicants possession of them

Appellants disagree with the Examiner's contention that the claimed polynucleotides encoding a variant of SEQ ID NO:2 must include a functional limitation for the encoded protein. Applicants reiterate the basic argument presented previously in the Response filed 2/24/03 that the specification provides an adequate written description of the claimed variants of SEQ ID NO:2 in terms of chemical and structural properties of SEQ ID NO:2 and that a recitation of functional characteristics is not an absolute requirement for fulfilling the written description requirement.

In addition, however, applicants submit that while the Examiner has cited literature identifying some of the difficulties that may be involved in predicting protein function, (i.e., Skolnick et al.) none suggests that functional homology cannot be inferred by a reasonable probability in this case. Most important, none contradicts Brenner's basic rule that sequence homology in excess of 40% over 70 or more amino acid residues yields a high probability of functional homology as well. At most, these articles individually and together stand for the proposition that it is difficult to make predictions about function with certainty.

The requirements necessary to fulfill the written description requirement of 35 U.S.C. 112, first paragraph, are well established by case law, some of which the Examiner cites in the

Final Office Action, at page 7.

> . . . the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed. Vas-Cath, Inc. v. Mahurkar*, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991)

Attention is also drawn to the Patent and Trademark Office's own "Guidelines for Examination of Patent Applications Under the 35 U.S.C. Sec. 112, para. 1", published January 5, 2001, which provide that :

> An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., **complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics**. What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. (Emphasis added)

Thus, the written description standard is fulfilled by both what is specifically disclosed and what is conventional or well known to one skilled in the art.

SEQ ID NO:2 is specifically disclosed in the application (see, for example, page 3, lines 4-6). Variants of SEQ ID NO:2 having at least 95% identity to SEQ ID NO:2 are described, for example, at page 3, lines 6-7. Incyte clones in which the nucleic acids encoding the human ARP-2 were first identified and libraries from which those clones were isolated are described, for example, at page 10, lines 12-22 of the Specification. Chemical and structural features of ARP-2 are described, for example, on page 10, line 23 through page 11, line 8. In particular, the specification describes specific structural and functional sequence motifs common to ASIP-related proteins a the top of page 11. Given SEQ ID NO:2, and the structural motifs characterizing SEQ ID NO:2 as an ASIP-related protein, one of ordinary skill in the art would recognize naturally-occurring variants of SEQ ID NO:2 having at least 95% sequence identity to SEQ ID NO:2. Accordingly, the Specification provides an adequate written description of the recited polypeptide sequences.

A. The Specification provides an adequate written description of the claimed "variants" of SEQ ID NO:2.

The Office Action has asserted that the claims are not supported by an adequate written description because:

> The specification does describe a description of the structure of a nucleic acid molecule encoding a variant of the polypeptide of SEQ ID NO:2 having an amino acid sequence that is at least 95% identical to SEQ ID NO:2
>
> (page 6 of the Final Office Action)

Such a position is believed to present a misapplication of the law.

1. The present claims specifically define the claimed genus through the recitation of chemical structure

Court cases in which "DNA claims" have been at issue commonly emphasize that the recitation of structural features or chemical or physical properties are important factors to consider in a written description analysis of such claims. For example, in *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993), the court stated that:

> If a conception of a DNA requires a precise definition, such as by structure, formula, chemical name or physical properties, as we have held, then a description also requires that degree of specificity.

In a number of instances in which claims to DNA have been found invalid, the courts have noted that the claims attempted to define the claimed DNA in terms of functional characteristics without any reference to structural features. As set forth by the court in *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997):

> In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function.

Thus, the mere recitation of functional characteristics of a DNA, without the definition of structural features, has been a common basis by which courts have found invalid claims to DNA. For example, in *Lilly*, 43 USPQ2d at 1407, the court found invalid for violation of the written description requirement the following claim of U.S. Patent No. 4,652,525:

> 1. A recombinant plasmid replicable in procaryotic host containing within its nucleotide sequence a subsequence having the structure of the reverse transcript of an mRNA of a vertebrate, which mRNA encodes insulin.

In *Fiers*, 25 USPQ2d at 1603, the parties were in an interference involving the following count:

> A DNA which consists essentially of a DNA which codes for a human fibroblast interferon-beta polypeptide.

Party Revel in the *Fiers* case argued that its foreign priority application contained an adequate written description of the DNA of the count because that application mentioned a potential method for isolating the DNA. The Revel priority application, however, did not have a description of any particular DNA structure corresponding to the DNA of the count. The court therefore found that the Revel priority application lacked an adequate written description of the subject matter of the count.

Thus, in *Lilly* and *Fiers*, nucleic acids were defined on the basis of functional characteristics and were found not to comply with the written description requirement of 35 U.S.C. §112; *i.e.*, "an mRNA of a vertebrate, which mRNA encodes insulin" in *Lilly*, and "DNA which codes for a human fibroblast interferon-beta polypeptide" in *Fiers*. In contrast to the situation in *Lilly* and *Fiers*, the claims at issue in the present application define polynucleotides or polypeptides in terms of chemical structure, rather than on functional characteristics. For example, the "variant language" of independent claim 1 recites chemical structure to define the claimed genus:

> 1. An isolated cDNA, or the complement thereof, encoding a protein having the amino acid sequence of SEQ ID NO:2, or a naturally occurring variant of SEQ ID NO:2 having at least 95% amino acid identity to SEQ ID NO:2.

From the above it should be apparent that the claims of the subject application are fundamentally different from those found invalid in *Lilly* and *Fiers*. The subject matter of the present claims is defined in terms of the chemical structure of SEQ ID NO:2. In the present case, there is no reliance merely on a description of functional characteristics of the polynucleotides recited by the claims. In fact, there is no recitation of functional characteristics. Moreover, if such functional recitations were included, it would add to the structural characterization of the recited polynucleotides. The polynucleotides defined in the claims of the present application recite structural features, and cases such as *Lilly* and *Fiers* stress that the recitation of structure is

an important factor to consider in a written description analysis of claims of this type. By failing to base its written description inquiry "on whatever is now claimed," the Office Action failed to provide an appropriate analysis of the present claims and how they differ from those found not to satisfy the written description requirement in *Lilly* and *Fiers*

2. The present claims do not define a genus which is "highly variant"

Furthermore, the claims at issue do not describe a genus which could be characterized as "highly variant." Available evidence illustrates that the claimed genus is of narrow scope.

In support of this assertion, the Examiner's attention is directed to the reference by Brenner et al., of record, ("Assessing sequence comparison methods with reliable structurally identified distant evolutionary relationships," Proc. Natl. Acad. Sci. USA (1998) 95:6073-6078). Through exhaustive analysis of a data set of proteins with known structural and functional relationships and with <90% overall sequence identity, Brenner et al. have determined that 30% identity is a reliable threshold for establishing evolutionary homology between two sequences aligned over at least 150 residues. (Brenner et al., pages 6073 and 6076.) Furthermore, local identity is particularly important in this case for assessing the significance of the alignments, as Brenner et al. further report that ≥40% identity over at least 70 residues is reliable in signifying homology between proteins. (Brenner et al., page 6076.). See also p. 31, lines 11-14 of the specification.

The present application is directed, *inter alia*, to ASIP proteins related to the amino acid sequence of SEQ ID NO:2. In accordance with Brenner et al, naturally occurring molecules may exist which could be characterized as ASIP proteins and which have as little as 40% identity over at least 70 residues to SEQ ID NO:2. The "variant language" of the present claims recites, for example, polynucleotides encoding "a naturally-occurring amino acid sequence having at least 95% sequence identity to the sequence of SEQ ID NO:2" (note that SEQ ID NO:2 has 1356 amino acid residues). This variation is far less than that of all potential ASIP proteins related to SEQ ID NO:2, i.e., those ASIP proteins having as little as 40% identity over at least 70 residues to SEQ ID NO:2.

3. The state of the art at the time of the present invention is further advanced than at the time of the *Lilly* and *Fiers* applications

In the *Lilly* case, claims of U.S. Patent No. 4,652,525 were found invalid for failing to comply with the written description requirement of 35 U.S.C. §112. The '525 patent claimed the benefit of priority of two applications, Application Serial No. 801,343 filed May 27, 1977, and Application Serial No. 805,023 filed June 9, 1977. In the *Fiers* case, party Revel claimed the benefit of priority of an Israeli application filed on November 21, 1979. Thus, the written description inquiry in those case was based on the state of the art at essentially at the "dark ages" of recombinant DNA technology.

The present application was filed in January 2001. Much has happened in the development of recombinant DNA technology in the 20 or more years from the time of filing of the applications involved in *Lilly* and *Fiers* and the present application. For example, the technique of polymerase chain reaction (PCR) was invented. Highly efficient cloning and DNA sequencing technology has been developed. Large databases of protein and nucleotide sequences have been compiled. Much of the raw material of the human and other genomes has been sequenced. With these remarkable advances one of skill in the art would recognize that, given the sequence information of SEQ ID NO:2, and the additional extensive detail provided by the subject application, the present inventors were in possession of the claimed polynucleotide variants at the time of filing of this application.

4. Summary

The Office Action failed to base its written description inquiry "on whatever is now claimed." Consequently, the Action did not provide an appropriate analysis of the present claims and how they differ from those found not to satisfy the written description requirement in cases such as *Lilly* and *Fiers*. In particular, the claims of the subject application are fundamentally different from those found invalid in *Lilly* and *Fiers*. The subject matter of the present claims is defined in terms of the chemical structure of SEQ ID NO:2 or SEQ ID NO:20. The courts have stressed that structural features are important factors to consider in a written description analysis of claims to nucleic acids and proteins. In addition, the genus of polynucleotides defined by the present claims is adequately described, as evidenced by Brenner et al and consideration of the claims of the '740 patent involved in *Lilly*. Furthermore, there have been remarkable advances in the state of the art since the *Lilly* and *Fiers* cases, and these advances were given no consideration whatsoever in the position set forth by the Office Action.

For all of the above reasons, applicants submit that they are in possession of the claimed invention, at least as recited in claims 1 and 3-8 and therefore request withdrawal of the rejection of claims under 35 U.S.C. § 112, first paragraph.

Claims 1 and 4-8 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection alleges in particular that:

- Claims 1 and 4 recite the terms "a naturally occurring variant" of [...] SEQ ID NO:2 and "a naturally occurring variant" of [...] SEQ ID NO:20", respectively. However, there does not appear to be proper and sufficient antecedent basis in the specification for the recitation of these terms in the claims. Therefore, recitation of the terms in the claims appears to introduce new matter and thereby violates the written description requirement set under 35 U.S.C. § 112, first paragraph..

The rejection is improper as the terms "naturally occurring" and "variant" are sufficiently described in the specification or known to the skilled artisan, such that one skilled in the art would recognize applicant's possession of "a naturally occurring variant".

Applicants submit that, having provided explicit support for the terms "naturally occurring" and "variant" in the specification, the combination of the terms in the phrase "naturally occurring variant" in the claims would be clearly understood to one skilled in the art as referring to a variant of SEQ ID NO:20, or of the polynucleotide encoding SEQ ID NO:2, that occurs in nature and that applicants clearly were in possession of such variants at the time the application was filed.

The terms "naturally occurring" are recited throughout the specification, in addition to being well understood in the art. For example, at page 7, line 13, "naturally occurring molecules"; at page 12, line 41, "naturally occurring gene"; and at page 13, line 2, "naturally occurring ARP". The term "variant" is likewise recited throughout the specification as well as specifically defined at page 9, lines 9-15 of the specification.

Thus the terms are sufficiently described in the specification that the skilled artisan would clearly recognize these descriptions as adequate antecedent basis for the use of the terms in the phrase "naturally occurring variant". Withdrawal of the rejection of claims 1 and 4-8 under 35 U.S.C. § 112, first paragraph is therefore requested.

Claims 3 and 4 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection alleges in particular that:

- Claim 3 recites the limitation "from about amino acid residue K189 to about amino acid residue Q236 of SEQ ID NO:2". However, there does not appear to be a proper and sufficient antecedent basis in the specification to support the recitation of this limitation in the claim. Therefore, recitation of the terms in the claims appears to introduce new matter and thereby violates the written description requirement set under 35 U.S.C. § 112, first paragraph.
- Claim 4 recites the limitation "comprising" in line 1. There does not appear does not appear to be a proper and sufficient antecedent basis in the specification to support the recitation of this limitation in the claim, since originally claim 1 was drawn to an isolated cDNA which is selected from (a) a nucleic acid of SEQ ID NO:20, or its complement, (b) a fragment of SEQ ID NO:20, which is SEQ ID NO:21, and (c) a naturally occurring variant of SEQ ID NO:20. Therefore, the recitation of the limitation "comprising" in the claim appears to broaden the scope of the claimed invention and thereby introduce new matter in violation of the written description requirement set under 35 U.S.C. § 112, first paragraph.

The rejection of claims 3 and 4 under 35 U.S.C. § 112, first paragraph, is overcome by the deletion of the terms "about" from claim 3, and "comprising" from claim 4

Claim 3 was amended in the Response to Final Office Action to delete the term "about" from the claim, and claim 4 was amended to delete the term "comprising" from the claim. Withdrawal of the rejection of claims 3 and 4 under 35 U.S.C. § 112, first paragraph is therefore requested.

Claim 4 stands rejected under 35 U.S.C. § 102(a) as being anticipated by Joberty et al. (Nature Cell Biology 2:531-539, 2000). The rejection alleges in particular that:

- Joberty et al teach a nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO:20. Claim 4 is drawn to a cDNA comprising a sequence of a nucleic acid sequence of SEQ ID NO:20 or its complement. The nucleic acid of the prior art has a polynucleotide sequence that comprises a sequence of the polynucleotide sequence set forth in SEQ ID NO:20. The specification teaches, "the singular forms of a, an, and the

include plural reference unless the context clearly dictates otherwise (specification, page 6, lines 12-13). Thus, consistent with the example set forth at page 6, "a sequence" as recited in claim 4, is read as a plurality of sequences, or a plurality of two or mor contiguous nucleotides of SEQ ID NO:20. Because the nucleic acid molecule of the prior art comprises one or more sequences of the polynucleotide sequence set forth in SEQ ID NO:20, the disclosure of the prior art is deemed anticipatory of the claimed invention.

The rejection may be overcome by amendment of the claims to recite "the nucleic acid sequence of SEQ ID NO:20 if the Examiner so wishes

Applicants submit that the definition referred to by the Examiner at page 6 of the specification clearly shows, by example of "a host cell", that "plural reference" by a singular term such as "a" or "an" merely means that a choice of several host cells, for example, such as host cell A, B, or C may be encompassed by the singular term "a host cell". By analogy, reference to "a sequence" could refer to any one of a number of recited sequences. However, having specifically recited "a nucleic acid sequence of SEQ ID NO:20" provides a context that clearly dictates otherwise as the specification also teaches, i.e., that SEQ ID NO:20 is the only sequence referred to in the claim.

However, if the Examiner so wishes, the claim may be amended to recite "the nucleic acid sequence of SEQ ID NO:20" if further clarification is necessary.

Claim 4 stands rejected under 35 U.S.C. § 102(b) as being anticipated by either Izumi et al. (Journal of Cell Biology 143:95-106, 1998) or NCI-CGAP (Data base GenBank Accession No. AI079538, 1998). The rejection alleges in particular that:

- Izumi or GenBank Accession No. AI079538 teach a nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO:20. The disclosure of the prior art is deemed anticipatory of the claimed invention for the same reasons given under anticipation by Joberty et al.

The rejection may be overcome by amendment of the claims to recite "the nucleic acid sequence of SEQ ID NO:20 if the Examiner so wishes

The arguments and proposed amendment to the claim discussed above in response to the rejection under anticipation by Joberty et al. are referenced and incorporated herein.

Due to the urgency of this matter, including its economic and public health implications, an expedited review of this appeal is earnestly solicited.

If the USPTO determines that any additional fees are due, the Commissioner is hereby authorized to charge Deposit Account No. **09-0108.**

This brief is enclosed in triplicate

Respectfully submitted,

INCYTE CORPORATION

Date: December 4, 2003

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APPENDIX - CLAIMS ON APPEAL

1. (Previously Presented) An isolated cDNA, or the complement thereof, encoding a protein having the amino acid sequence of SEQ ID NO:2, or a naturally occurring variant of SEQ ID NO:2 having at least 95% amino acid identity to SEQ ID NO:2.

3. (Previously Amended) An isolated cDNA, or the complement thereof, encoding a protein having the amino acid sequence of SEQ ID NO:2, or an antigenic epitope of SEQ ID NO:2 from amino acid residue K189 to amino acid residue Q236 of SEQ ID NO:2.

4. (Previously Amended) An isolated cDNA selected from:

a) a nucleic acid sequence of SEQ ID NO:20 or the complement thereof;

b) a fragment of SEQ ID NO:20 consisting of SEQ ID NO:21 or the complement thereof; and

c) a naturally occurring variant of SEQ ID NO:20 having at least 90% sequence identity to SEQ ID NO:20.

5. (Original) A composition comprising the cDNA or the complement of the cDNA of claim 1.

6. (Original) A vector comprising the cDNA of claim 1.

7. (Original) A host cell comprising the vector of claim 6.

8. (Original) A method for using a cDNA to produce a protein, the method comprising:

a) culturing the host cell of claim 7 under conditions for protein expression; and

b) recovering the protein from the host cell culture.